

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 21731 wo-ws		FOR FURTHER ACTION	See Form PCT/IPEA/416																								
International application No. PCT/EP2004/005924	International filing date (day/month/year) 02.06.2004	Priority date (day/month/year) 06.06.2003																									
International Patent Classification (IPC) or national classification and IPC																											
Applicant ROCHE DIAGNOSTICS GMBH																											
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand		Date of completion of this report																									
Name and mailing address of the IPEA/EP		Authorized officer																									
Facsimile No.		Telephone No.																									

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/005924

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

international search (Rule 12.3 and 23.1(b))
 publication of the international application (Rule 12.4)
 international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished
 the description:

pages 1-17 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19 18.01.2005 with letter

nos.* 1-23 received by this Authority on of 13.01.2005

nos.* _____ received by this Authority on _____

the drawings:

sheets 1/4-4/4 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

the description, pages _____
 the claims, nos. 24 _____
 the drawings, sheets/figs _____
 the sequence listing (*specify*): _____
 any table(s) related to sequence listing (*specify*): _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages _____
 the claims, nos. _____
 the drawings, sheets/figs _____
 the sequence listing (*specify*): _____
 any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/005924Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1, 2, 8, 9</u>	YES
	Claims <u>3-7, 10-23</u>	NO
Inventive step (IS)	Claims <u>1, 2, 8, 9</u>	YES
	Claims <u>3-7, 10-23</u>	NO
Industrial applicability (IA)	Claims <u>1-23</u>	YES
	Claims _____	NO

2. Citations and explanations (Rule 70.7)

1. Reference is made to the following documents:

D1: US-A-4 622 974 (COLEMAN JERRY T ET AL)
 18 November 1986 (1986-11-18)

D2: WO 02/100274 A (AMIRA MEDICAL; ROE JEFFREY N
 (US); ROE STEVEN N (US))
 19 December 2002 (2002-12-19).

2. Document D1 is considered to be the prior art closest to the subject matter of claim 1. Said document (the references in parentheses are to D1) discloses a system for analysing a sample to be investigated, which system comprises a test field ("sample cavity" 36, column 4, line 34; column 7, line 55; figure 1; claim 1) with a reagent (column 7, lines 53-68) which, when contacted with an analyte contained in the sample reacts in such a way that an optically detectable change occurs in the test field, and further comprises at least one light-conducting element ("optical fiber" 16, column 3, line 37; figure 1 and claim 1) with a first, distal end disposed in the region of the test field and a second, proximal end into which

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/005924

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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light can be launched such that light is conducted from the second end to the test field and conducted away from the test field through the same, or a further, light-conducting element, and a lancet (needle 18, column 3, line 39; figure 1; claim 1) with a lancet point which is located in the region of both the distal end and the test field in such a way that, during insertion, the lancet point projects beyond the distal end of the light conductor and also projects beyond the test field (figure 1).

The subject matter of claim 1 differs from the arrangement known from D1 in that the lancet is, at least in part, surround by the light-conducting element.

The problem addressed by the present invention can consequently be regarded as that of facilitating the insertion of the lancet using conventional release mechanisms whilst at the same time surrounding the lancet in a protective manner before and after its insertion.

A combination of features as per claim 1 of the present application is neither known nor readily derivable from D1 or from the remaining available documents. Claim 1 therefore satisfies the requirements of PCT Article 33(2) to (4).

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/005924

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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3. **Claims 2, 8 and 9**, in so far as they are dependent on claim 1, likewise satisfy the requirements of the PCT in respect of novelty and inventive step.

4. The further independent claim, claim 3, contains an additional feature instead of the lancet surrounded by the light-conducting element, namely that the first, distal end of the light-conducting element is fixed to the test field. However, this feature is known from D1 (see column 4, lines 15-26). Although in D1 the light-conducting element ("optical fiber" 16) can be moved, using a micrometer screw for example, for the purpose of calibration (column 6, lines 13-55), the measured distance thus obtained is individually adjusted ("optical fiber 16 is positioned at a selected distance...of 0.9mm", column 4, lines 21-24) and is maintained during measurement (column 6, lines 3-12).

Thus, the subject matter of **claim 3** lacks novelty (PCT Article 33(2)) and therefore fails to satisfy the requirements of PCT Article 33(1).

5. Dependent **claims 4-7 and 10-23** contain no features which, combined with the features of any claim to which they refer, meet the PCT requirements for novelty and/or inventive step (see in particular documents D1 and D2 and the corresponding passages of text cited in the search report).